K003743

SYNTHES®

FEB - 9 2001

3.0 Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
DEVICE NAME:	Synthes Modified Bioresorbable Suture Anchor System
COMMON OR USUAL NAME:	Fastener, Fixation, Biodegradable, Soft Tissue
DEVICE CLASSIFICATION:	Class II
PREDICATE DEVICE:	Modified Mitek PANALOK 3.5mm Absorbable Suture Anchor System
DESCRIPTION:	Synthes Modified Bioresorbable Suture Anchor System includes three pre-assembled components intended for surgical implantation of a suture anchor in bone. The implant components include a Bioresorbable Suture Anchor and a length of polyester suture, which has been pre-threaded into the suture anchor. Also included is an Inserter used to drive the threaded suture anchor. The pre-threaded suture anchor is mounted by friction fit onto the Inserter. These pre-assembled components have been combined in a procedure ready, sterile package intended for single use.
INTENDED USE:	To repair ligamentous and tendinous defects in the shoulder, knee, foot, ankle, hand and wrist, such as Bankart repair, SLAP lesion repair, Achilles tendon repair/reconstruction, patellar ligament and tendon avulsion repair and medial/lateral collateral ligament repair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2001

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K003743
Trade Name: Synthes Modified Bioresorbable Suture Anchor System
Regulatory Class: II
Product Codes: MAI, HWC, GAS
Dated: December 1, 2000
Received: December 4, 2000

Dear Ms. Silvestri:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K003743

Device Name: Synthes Modified Bioresorbable Suture Anchor System

Indications: To repair ligamentous and tendinous defects in the shoulder, knee, foot, ankle, hand and wrist, such as Bankart repair, SLAP lesion repair, Achilles tendon repair/reconstruction, patellar ligament and tendon avulsion repair and medial/lateral collateral ligament repair.

Contraindications: Bone of poor density (i.e., osteopenic bone), where holding strength of the anchor may be compromised, and active infection.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003743